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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,668	04/21/2004	Igor Waysbeyn	H308-001-PAT	4917

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/828,668	Applicant(s) WAYSBEYN ET AL.	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 29-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/21/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the barb profile of claim 25 having a partial convex and partial concave profile must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

Claims 11, 14, 19, and 22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Each claim positively recites a portion of the body which is considered non-statutory subject matter.

Claim 11 recites, "device is coupled to the blood vessel".

Claim 14 recites, "graft is longer than the aneurysm".

Claim 19 recites, "cone... smaller than an internal diameter of the blood vessel".

Claim 22 recites, "barbs... 1 to 4 times the thickness of the blood vessel's wall".

It is suggested to insert language such as adapted to, capable of, etc. to overcome the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "said suitable positioning" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitations "said truncated cone" and "said tubular graft" in lines 1 and 2. There is insufficient antecedent basis for these limitations in the claim.

Claim Objections

Claim 24 is objected to because of the following informalities: The claim is missing a period at the end. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-15 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Randall et al. (US 2003/0158595 A1). Randall discloses a vascular device (fig.6) comprising a graft (40) with proximal (top) and distal (bottom) ends, a first docking head (10) provided at the proximal end and a second docking head (16 or 18) provided at the distal end. Randall discloses the graft (40) to be tubular and bifurcated, see fig.6). Randall discloses the docking heads (10, 16, 18) to be capable of moving relative the stent (they are not disclosed to be sewn or adhered to the graft therefore are inherently capable of moving prior to expansion). Randall discloses attachment of the docking heads upon expansion, by clips/barbs (14). Randall discloses the docking heads (10, 16, 18) to be separate modules than the graft (40).

Claims 11, 12, 15, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Elliot (US 2003/0236567 A1). Elliot discloses a vascular device (figs.3a-3c) comprising a graft (12) with proximal (top) and distal (bottom) ends, a first docking head (16) provided at the proximal end and a second docking head (multiple docking heads, P0026) provided at the distal end. Elliot discloses the graft (12) to be tubular (see figs). Elliot discloses attachment of the

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docking heads by sutures or bonding (P0030). Elliot discloses the cone (16) to be an extension of the graft everted over itself (fig.3b).

Claims 11-19, 21, 23, 26, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Haverkost (US 2003/0074055 A1). Haverkost discloses a vascular device (fig.3) comprising a graft (36) with proximal (top) and distal (bottom) ends, a first docking head (30) provided at the proximal end and a second docking head (32, 34) provided at the distal end. Haverkost discloses the graft (36) to be tubular and bifurcated, see fig.3. Haverkost discloses the docking heads (30, 32, 34) to be capable of moving relative the graft (as they are disclosed to be separate modules, see fig.2,3). Haverkost discloses attachment of the docking heads upon expansion, by clips/barbs (inner and outer barbs, P0033). Haverkost discloses the docking heads to be conical (shown tapered in fig.3 to expand to the naturally tapered branches in the vasculature and conical in fig.5), the cones having outward barbs (P0033). Haverkost discloses the cones to be elastic (self expanding). Haverkost discloses the cones (30, 32, 34) to have slits (slits being the apertures between struts in mesh stents) allowing it to curtail (mesh stents shorten upon expansion).

Claims 11-13, 15-19, 21, 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (US 6,729,356 B1). Baker discloses a vascular device (fig.5-7) comprising a graft (134) with proximal (top) and distal (bottom) ends, a first docking head (140+138) provided at the proximal end and a second docking head (fig.18; col.4, lines 29-41) provided at the distal end. Baker discloses the graft (134) to be tubular and bifurcated (col.2, lines 9-14, 18-

24). Baker discloses attachment of the docking heads upon expansion, by clips/barbs (139, 47). Baker discloses the docking heads to be conical (fig.7; col.2, lines 35-42), the cones having outward barbs (47, 139) that are concave (fig.3) or convex (43) and concave (45, fig.1, 7). Baker discloses the cones to be elastic (see figs).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haverkost (US 2003/0074055 A1). Haverkost discloses cones having diameters and barbs having lengths, however is silent to mention specific dimensions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed dimensions since wherein the general conditions of a claim are disclosed in the prior art (diameter, length), it is not inventive to find the optimum working conditions by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER